K080822 (pg. 1 of 2)

510(k) Summary
(21 CFR Part 807.92)

JUL - 2 2008

A. Submitter Information

Submitter's Name:	Theken Spine, LLC
Address:	1800 Triplett Blvd. Akron, Ohio 44306
Telephone Number:	330-475-8600
Fax Number:	330-773-7697
Contact Person:	Dale Davison
Date Prepared:	7/01/2008

B. Device Information

Trade Name:	Vu aPOD Intervertebral Body Fusion Device
Common Name:	Intervertebral Body Fusion Device
Classification Name:	Spinal Intervertebral Body Fusion Device (per 21 CFR 888.3080)
Device Classification:	Class II (per 21 CFR 888.3080) Panel: Orthopedic, Product Code: MAX
Predicate Device:	Theken Surgical, LLC REVEAL VBR System (K050058) DePuy Acromed Lumbar I/F Cage (P960025) Spinal Elements, Lucent Magnum (K073348)
Material Composition:	Polyetheretherketone (PEEK-OPTIMA LT) per ASTM F-2026 Tantalum per ASTM F-560 Titanium 6Al-4V ELI per ASTM F-136
Subject Device Description:	The Vu aPOD Intervertebral Body Fusion Device is comprised of PEEK-OPTIMA® LT cages which can be used in combination with an optional titanium spin plate. The cages include toothed spikes on the top and bottom surfaces to engage with the superior and inferior end plates of neighboring vertebral bodies to resist rotation and migration. The cage shape and open center allow for bony in-growth in and around the implant. A single cage is sufficient to be used at each intervertebral level.
Intended Use:	The Theken Spine Vu aPOD Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft material. The Theken Spine Vu aPOD Intervertebral Body Fusion Device is intended for use with supplemental fixation such as the Coral Spinal System or the BodyForm Thoracolumbar Fixation System. Degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

C. Substantial Equivalence

The technological characteristics of the Vu aPOD Intervertebral Body Fusion Device are similar to the predicate device REVEAL Vertebral Body Replacement (K050058), Manufactured by Theken Surgical, LLC, the DePuy Acromed Lumbar I/F Cage (P960025), and the Spinal Elements Lucent Magnum (K073348)

The subject device similarities include:

- Indications for use
- The same basic design
- The same operating principle
- The same materials
- Used in conjunction with supplemental fixation
- The same manufacturing environment
- The same sterilization process
- The same packaging configurations

Theken Spine believes that sufficient evidence exists to reasonably conclude that the Vu aPOD Intervertebral Body Fusion Device is substantially equivalent to the predicate device REVEAL Vertebral Body Replacement (K050058), manufactured by Theken Surgical, LLC, the DePuy Acromed Lumbar I/F Cage (P960025), and the Spinal Elements Lucent Magnum (K073348). This is based on the design concept, the use of established, known materials, feature comparisons, mechanical testing, indications for use, pre-production quality assurance planning and engineering analysis. All implants represent a basic design concept in terms of safety and effectiveness, and differ only in minor details.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Theken Spine, LLC
% Mr. Dale Davison
1800 Triplett Boulevard
Akron, OH 44306

SEP 12 2011

Re: K080822
Trade/Device Name: Vu a·POD Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: May 15, 2008
Received: June 3, 2008

Dear Mr. Davison:

This letter corrects our substantially equivalent letter of July 2, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080822

Device Name: Vu aPOD Intervertebral Body Fusion Device

Indications For Use:

The Theken Spine Vu aPOD Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The interior of the spacer component may be packed with autogenous bone graft material. The Theken Spine Vu aPOD Intervertebral Body Fusion Device is intended for use with supplemental fixation such as the Coral Spinal System or the BodyForm Thoracolumbar Fixation System.

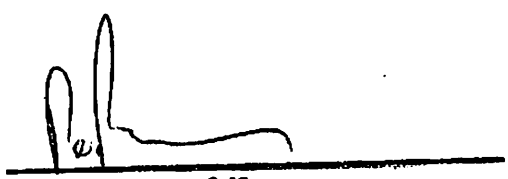
Degenerative disc disease (DDD) is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080822